REMARKS

The applicant respectfully requests reconsideration of claims 60-77 in view of the foregoing amendment. Claims 60 and 69 are amended to emphasize that the structural strands are altered, and thus are in their selected nominal shapes.

A. Claims 61 and 69 have been rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to distinctly claim the present invention.

Claims 61 and 70 (it is believed that claim 70 rather than 69 was intended) have been amended to remove the phrase "that prevents any substantial leakage of body fluids including blood." Accordingly, it is submitted that these claims comply with Section 112, second paragraph.

B. Claims 60-77, and various subsets of these claims, stand rejected under the judicially created doctrine of obviousness-type double patenting, as allegedly unpatentable over patented and pending claims, as follows:

(1) claims 60-77, with respect to claims 1-6, 11-13 and 15-22 of U.S. Patent No. 6,689,162;

(2) claims 61, 62, 64 and 67, with respect to claims 1, 2, 6 and 8 of U.S. Patent No. 6,342,068;

(3) claims 61 and 66, with respect to claims 1-3 of U.S. Patent No. 6,019,768;

(4) claims 61, 62, 64 and 67, with respect to claims 1, 6, and 8 of U.S. Patent No. 6,592,617; and

(5) claims 61, 62, 64 and 67, with respect to claims 54, 55, 68, 73-75, 83, 90, 92 and 93 of co-pending U.S. Application Serial No. 10/619,888.

In connection with these rejections, it is asserted that the conflicting claims are not patentably distinct from each other because the patented or copending claims allegedly anticipate claims of this application. The applicant, respectfully, does not acquiesce in these assertions. However, given the negligible impact of a terminal disclaimer on the term of a patent eventually issued on this application, the applicant is agreeable to filing a terminal disclaimer.

Accompanying this amendment is a terminal disclaimer, signed on behalf of the assignee of the present application, disclaiming any portion of the term of a patent issuing on this application that otherwise might extend beyond: (1) the full statutory term of U.S. Patent No. 6,689,162; (2) the full statutory term of U.S. Patent No. 6,342,068; (3) the full statutory term of U.S. Patent No. 6,019,768; (4) the full statutory term of U.S. Patent No. 6,592,617; and (5) the full statutory term of a patent issuing on U.S. Patent Application S/N 10/619,888. This application, and the aforementioned patents and copending patent application, are commonly owned. Accordingly, it is submitted that these claims no longer are subject to the obviousness-type double patenting rejections.

C. Claims 60-64, 66-73, and 75-77 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,834,755 (Silvestrini).

The present invention is directed to a medical prosthesis or implantable device including an interbraiding of a plurality of structural strands. In some cases, the interbraiding also includes textile strands that are more compliant than the structural strands. In any case, the structural strands have respective nominal strand shapes when they are in a relaxed state under no external stress. The structural strands are elastically deformable away from their respective nominal strand shapes. Each structural strand is metal, and is adapted to be altered to acquire a selected nominal strand shape, different from an original nominal strand shape, in response to a controlled plastic deformation treatment prior to interbraiding.

The structural strands are so altered, and in their respective selected nominal strand shapes form windings having tubular profiles. The structural strands have selected orientations within the prosthesis to collectively impart to the prosthesis a tubular predetermined nominal configuration corresponding to the tubular profiles of the structural strands.

Thus, prostheses constructed according to the present invention uniquely incorporate the following features:

1. Selective shaping: Each of the structural strands is amenable to selective shaping in which the nominal shape of the strand, i.e. the shape assumed by the strand when in a relaxed state under no external stress, is altered. Each of the structural strands has a selected nominal shape in lieu of its original nominal shape. The selected nominal shape is different from the original nominal shape.

2. Shapable by plastic deformation: Each of the structural strands is metal, and is adapted to acquire its selected nominal shape in response to a controlled plastic deformation treatment.

3. Tubular nominal strand shape: The selected nominal shape of each structural strand is tubular, in that the strand forms a winding having a tubular profile.

4. Prosthesis–shaping strand orientation: The altered strands have selected orientations within the prosthesis, and thus cooperate to impart a tubular predetermined nominal shape to the prosthesis.

5. Correspondence of prosthesis predetermined nominal configuration and strand nominal shapes: The predetermined nominal shape of the prosthesis corresponds to the selected nominal shapes of the structural strands.

The specification discloses preferred embodiment prostheses that illuminate each of the above features. Controlled plastic deformation or shaping can be accomplished using a shaping pulley. Each shaped structural strand forms a winding with a tubular profile, more particularly a helix. In preferred prostheses, the structural strands cooperate to form first and second sets of helices running in respective first and second opposite directions, thus to impart a tubular shape to the prosthesis. Finally, there is a correspondence of the prosthesis predetermined nominal configuration with the strand selected nominal shapes, in that the tubular profile defined by the prosthesis matches the tubular profiles of the helical strands.

Prior to the present invention, it was known to form prostheses by interbraiding multiple strands, including interbraiding elastic strands to form radially self-expanding prostheses. In such devices, the individual strands form windings with tubular profiles, typically helical windings. The strands, however, are not in their nominal shapes. Rather, each strand is biased into and maintained in its helical shape by the "external forces" from the other strands interbraided with it. Thus, even though the prosthesis as a whole may assume a nominal prosthesis configuration when subject to no external stress, each of the structural strands stores an elastic restoring force. If a user removed one of the elastic strands from the prosthesis, that strand would respond to its internal elastic restoring force, tending to return to its nominal shape, typically linear as pointed out in the present specification (page 13, lines 12-14).

Prostheses constructed according to this traditional approach are workable, and have been used successfully for years. This notwithstanding, they are subject to several problems, one of which is the tendency to unravel. One approach to counteract this problem is to weld or otherwise join the resilient strands to each other, either at the opposite ends of the prosthesis, or at all of the crossing points or intersections of the strands. For example, U.S. Patent No. 4,834,755 (Silvestrini et al.) advises fusing the free ends of the fibers at the edge of the device, by ultrasonic welding or by dipping the edge of the device in a suitable coating material (column 8, lines 32-36).

Another problem is the lack of sufficient predictability and control over prosthesis contractions and expansions. One prior art approach to this problem, taught in U.S. Patent No. 4,655,771 (Wallsten), is to secure longitudinally extending elastic strings or bands to the prosthesis. The longitudinal members are elastically stretched as the prosthesis is radially contracted by an external force, and tend to radially expand the prosthesis when the external force is removed.

A salient feature of the prosthesis constructed according to the present invention is the correspondence between the nominal configuration of the prosthesis, and the selected nominal shapes of the structural strands. Because of this correspondence, the structural strands are not loaded with internal elastic restoring forces when the prosthesis is in its nominal configuration. Rather, each strand likewise is in its nominal shape, thus to eliminate or minimize the elastic restoring forces present in the helical structural strands of prior art devices.

As a result, the tendency to unravel is considerably diminished, and prosthesis expansion and contraction behavior can be more reliably determined by the size, winding angle, material, etc. of the structural strands. Accordingly, braided prostheses can be designed with more precision to suit particular treatment needs, and can be used in more demanding treatment environments.

The Silvestrini patent discloses a triaxially-braided prosthesis for repairing or replacing soft tissue, primarily ligaments. The fibers include longitudinally extending fibers 9, and weft fibers 11 and 13 wound helically in opposite directions. When the prosthesis is stretched, longitudinal fibers 9 bear most of the load at first. As further stretching brings fibers 11 and 13 closer to a longitudinal alignment, these fibers more effectively resist further stretching, thus

sharply increasing the load required to achieve further elongation. This is said to duplicate ligament behavior.

Silvestrini teaches that its fibers (at least fibers 11 and 13) can be prepared by extruding a gel or dope to form a fiber, and then drawing the fiber at an elevated temperature (column 6, lines 53-59). This would be expected to yield the substantially linear nominal shape, noted in the present specification as the typical nominal shape of the structural strands before they are treated to acquire the selected nominal shapes. There is no further disclosure in Silvestrini regarding strand or fiber shaping. No controlled plastic deformation treatment is disclosed or suggested.

The independent claims subject to this rejection are claims 60 and 69. Presumably with respect to both of these claims, it is contended in the present action (page 6, top) that the selected orientations of the fiber sets in Silvestrini "can be of the strands of the braided device in relaxed state and not necessarily the strands before interbraiding."

This contention is respectfully traversed. It implies that when a prosthesis or other device composed of helical or otherwise tubularly wound fibers is "relaxed," then it anticipates the claim (60 or 69). This ignores the fact that both claims clearly distinguish between the selected nominal shape of each structural strand, and the predetermined nominal configuration of the prosthesis. The features of claim 60 (and likewise, claim 69) are not met simply by a prosthesis having a "relaxed" state. In addition, these claims provide that each structural strand has the helical or otherwise tubular nominal shape in and of itself, and that the structural strands have selected orientations within the prosthesis to impart to the prosthesis a tubular predetermined nominal shape. This is in contrast to the prior art devices in which the interbraided fibers or strands are maintained in helical shapes against respective internal elastic restoring forces, i.e. elastically deformed away from their more linear nominal shapes.

Finally, Silvestrini fails to teach the feature of correspondence of the predetermined nominal configuration of the prosthesis, to the tubular profiles of the individual structural strands, which again is found in both claims 60 and 69.

In short, none of the aforementioned features 1 through 5 is disclosed or even suggested in Silvestrini, which as noted above discloses no selective shaping of its fibers. Based on the only fiber preparation method disclosed in Silvestrini, one skilled in the art is led to conclude that the fiber nominal shape, if any, is linear. Accordingly, assuming arguendo that the materials

in Silvestrini and the presently claimed devices are identical, there is a distinct failure on the part of Silvestrini to teach the features of amenability to selective shaping, plastic deformation, tubular nominal strand shapes, prosthesis-shaping strand orientation, and correspondence of prosthesis/strand nominal shapes.

In connection with this rejection, it is contended in the present action (page 6, top) that Silvestrini's fibers "are inherently both elastic and plastic in that they are not perfectly rigid."

This contention is traversed. Those of skill in the art are aware that materials can vary considerably with respect to properties such as elasticity and ductility (susceptibility to plastic, as opposed to elastic, deformation). The preferred fiber materials in Silvestrini are synthetic polymers, for example cross-linked high molecular weight polyethylene. See column 5, lines 7-9, and column 6, lines 59-64. Such materials are known to possess elasticity, but also to lack any measurable ductility. They are not adapted for plastic deformation. Silvestrini mentions stainless steel as an alternative material. However, steels can range from highly ductile to highly brittle, depending on a variety of factors including their carbon content, the nature of their heat treatment, and the rate at which they are cooled.

To whatever extent the phrase "both elastic and plastic" is meant to convey the limitation in claims 60 and 69 that the structural strands are elastically deformable away from their nominal shapes, and further are adapted to be altered by controlled plastic deformation to acquire different nominal shapes, there is no foundation for the contention that any material "not perfectly rigid" is "inherently both elastic and plastic." Further, given that stainless steel need not have any discernable ductility, and that Silvestrini merely mentions stainless steel and suggests no need or desire for ductility in its fibers, Silvestrini fails to teach or suggest a fiber material that is "inherently both elastic and plastic."

Accordingly, the Silvestrini patent fails to anticipate the prosthesis of claim 60, and likewise fails to anticipate the device of claim 69.

Claims 61-64 and 66-68 depend on claim 60 and are patentable for the reasons given in support of claim 60.

Claim 62 is patentable, further, for the failure of Silvestrini to disclose or suggest fibers with helical selected nominal shapes. Silvestrini's fibers 11 and 13 are helical, and are present in

a ligament prosthesis that as a whole could well have a nominal (relaxed) configuration. This, however, does not teach that each fiber 11/13, in and of itself, is in its nominal or relaxed shape when helical. The distinction between the claimed predetermined nominal configuration of the prosthesis, and the selected nominal shapes individual structural strands, has been explained above.

In the present action (page 6) it is contended that Silvestrini fiber sets 11 and 13 "are in a helical shape and together impart the shape to the device."

This contention is respectfully traversed. Fibers 11 and 13 of Silvestrini are helical in the finished device. However, given the absence of any teaching that these fibers are controllably plastically deformed into helical shapes, one skilled in the art is led to conclude that the fibers are forced into their helical shapes by the external forces applied by other fibers in the braid. Further, assuming arguendo that Silvestrini's fibers, although elastically deformed, still "impart" the prosthesis shape, this fails to teach the feature in claims 60 and 69 that the predetermined nominal configuration of the prosthesis structure corresponds to the tubular profiles of the structural strands.

Claim 66 is patentable, further, for the failure of Silvestrini to disclose monofilament structural strands. In connection with this claim, it is contended in the present action (page 6, bottom) that the claim is met "when one considers the claimed structural strands to be those of fiber set 9 and one of set 11 or 13."

Claims 60 and 69 require structural strands that are monofilaments and form windings having tubular profiles. The examiner's proposed use of fibers 9 and 11 (or 9 and 13) yields a combination of first fibers (9) that are monofilaments but do not form windings that have tubular profiles, and second fibers that form windings with tubular profiles but are not monofilaments. This fails to anticipate the claimed combination.

Claims 70-73 and 75-77 depend on claim 69 and are patentable for the reasons given in support of claim 69.

Claim 71 is patentable, further, for the failure of Silvestrini to teach helical selected nominal shapes for any of its fibers. As previously explained, the presence of helical fibers in a

prosthesis which might have a prosthesis nominal shape or configuration, is not equivalent to the fibers themselves being in their respective nominal shapes when helical.

Claim 75 is patentable, further, for the failure of Silvestrini to teach structural strands that are monofilaments and form windings having tubular profiles, as explained above in connection with claim 66.

Claims 65 and 74 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Silvestrini in view of U.S. Patent No. 5,282,867 (Mikhail).

Mikhail disposes a prosthetic knee joint including a femoral component mounted to the femur, and a tibial component mounted to the tibia. The femoral and tibial components are mounted to pivot relative to each other. The components can be formed from a metal such as a cobalt chrome alloy or a cobalt chrome molybdenum alloy, a titanium alloy, or stainless steel. If desired, the prosthetic knee can include collateral ligaments joined between the femoral and tibial components. The collateral ligaments include strands of synthetic, non-reactive, non-absorbable biocompatible material such as Gore-Tex, which refers to a polymer, specifically expanded polytetrafluoroethylene (ePTFE).

In the present action (page 7, top), it is contended that Mikhail teaches making "similar implants" out of a cobalt-chrome-molybdenum alloy. In Mikhail, however, this alloy is used to form the essentially rigid femoral and tibial components. These components, lacking any discernable elasticity or ductility, provide no motive to one skilled in the art to employ the same alloy in a prosthetic application that requires both elasticity and ductility.

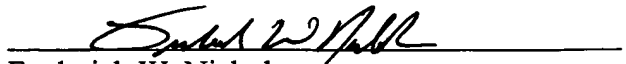
Accordingly, claims 65 and 74 are patentable over the Silvestrini/Mikhail combination.

In summary, claims 60-77 incorporate subject matter patentable over the prior art of record. An early and favorable action allowing these claims is respectfully requested.

Respectfully submitted,

Boston Scientific Scimed, Inc.

Dated: February 28, 2005

By: 

Frederick W. Niebuhr
Registration No. 27,717
Customer No. 23452

CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.8, I hereby certify that this Amendment in Application Serial No. 10/775,961 is being deposited with the U.S. Postal Service by first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of deposit indicated below.

Date of Deposit: February 28, 2005

Geralyn M. Vita

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